REMARKS

Reconsideration in view of the foregoing amendments and following remarks is respectfully requested.

Amendments to the title, specification and abstract are editorial in nature and have been made to correct errors in spelling, grammar, and punctuation; to provide consistency in terminology throughout the entire application; and to otherwise eliminate informalities existing in the original description. No new matter has been added. Paragraph numbers have been added to the "substitute" specification, but are not indicated on the marked-up copy.

A parts list is now being submitted.

FIGS. 15 and 16 are being deleted.

Amendments to the claims are editorial in nature, and no new matter has been added. Where applicable, subparagraphs in the claims have now been identified with lower case letters.

If there are any further issues yet to be resolved to advance the prosecution of this patent application to issue, the Examiner is requested to telephone the undersigned counsel.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

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Attachments: Substitute specification and abstract
Marked-up copy of original specification and abstract
New Parts List

MYFILES\PLEAD\PL4693

~~Attorney Docket No. 2856.06US02~~

PROTECTIVE SYSTEM OR APPARATUS INCLUDING GUIDEWIRE HAVING DEPLOYABLE SHEATHLESS ~~PROTECTIVE~~ FILTER AND METHOD UTILIZING SAME

RELATED APPLICATION

This application claims the benefit of U.S. Provisional Application No. 60/437,166, filed December 30, 2002, incorporated herein in its entirety by reference.

FIELD OF THE INVENTION

The present invention relates generally to the field of vascular medical devices. More specifically, the present invention relates to a ~~guidewire~~ protective system or apparatus for use in vascular procedures that ~~produces~~ includes a deployable ~~convex~~ filter that is sheathless ~~without the use of a sheath~~.

BACKGROUND OF THE INVENTION

Arterial disease involves damage that happens to the arteries in the body. Diseased ~~vessels~~ arteries can become plugged with thrombus, plaque, or grumous material that may ultimately lead to a condition known as ischemia. Ischemia refers to a substantial reduction or loss of blood flow to the heart muscle or any other tissue that is being supplied by the artery and can lead to permanent damage of the affected region. While arterial disease is most commonly associated with the formation of hard plaque and coronary artery disease in the heart, similar damage can happen to many other vessels in the body, such as the peripheral vessels and cerebral vessels, due to the build up of hard plaque or softer thrombus or grumous material within the lumen of an artery or vein.

A variety of vascular medical devices and procedures have been developed to treat diseased vessels. The current standard procedures include bypass surgery (where a new blood vessel is grafted around ~~the~~ a narrowed or blocked artery) and several different types of non-surgical interventional vascular medical procedures, including, angioplasty (where a balloon on a catheter is inflated inside ~~the~~ a narrowed or blocked portion of ~~the~~ an artery in an attempt to push back ~~the~~ plaque or thrombotic material), stenting (where a metal mesh tube is expanded against ~~the~~ a narrowed or blocked portion of ~~the~~ an artery to hold back ~~the~~ plaque or thrombotic material), and debulking techniques in the form of atherectomy (where some type of high speed or high power mechanism is used to dislodge ~~the~~ hardened plaque) or thrombectomy (where some type of mechanism or infused fluid is used to dislodge grumous or thrombotic material). In each of these interventional vascular medical procedures, a very flexible guidewire is routed through the patient's vascular system to a desired treatment location and then a catheter that includes a device on the distal end, appropriate for the given procedure, is tracked along the guidewire to the treatment location.

Although interventional vascular procedures avoid many of the complications involved in surgery, there is a possibility of complications if some of the plaque, thrombus or other material breaks free and flows downstream in the artery or other vessel, potentially causing a stroke, a myocardial infarction (heart attack), or other tissue death. One solution to this potential complication is to use some kind of occlusive device or filtering device to block or screen the blood flowing downstream of the treatment location.

The use of a protective device in the form of an occlusive device or filtering device as part of a vascular procedure is becoming more common in debulking procedures performed on heart bypass vessels. Most heart bypass vessels are harvested and transplanted from the

saphenous vein located along the inside of the patient's leg. The saphenous vein is a long, straight vein that has a capacity more than adequate to support the blood flow needs of the heart. Once transplanted, the saphenous vein is subject to ~~arterial disease caused by~~ a buildup of plaque or thrombotic materials ~~that build up~~ in the grafted arterial lumen. Unfortunately, the standard interventional vascular treatments for debulking are only moderately successful when employed to treat saphenous vein coronary bypass grafts. The complication rate for a standard balloon angioplasty procedure in a saphenous vein coronary bypass graft is higher than in a native vessel with the complications including embolization, "no-reflow" phenomena, and procedural related myocardial infarction. Ather~~o~~ectomy methods including directional, rotational, and laser devices are also associated with a high degree of embolization resulting in a greater likelihood of infarction. The use of stents for saphenous vein coronary bypass grafts has produced mixed results. Stents provide for less restenosis, but they do not eliminate the risk of embolization and infarction incurred by standard balloon angioplasty.

In order to overcome the shortcomings of these standard non-surgical interventional treatments in treating saphenous vein coronary bypass graft occlusion, embolic protection methods utilizing a protective device distal to the lesion have been developed. The protective device is typically a filter or a balloon. Use of a protective device in conjunction with an ather~~o~~ectomy or thrombectomy device is intended to prevent emboli from migrating beyond the protective device and to allow the embolic particles to be removed, thereby subsequently reducing the risk of myocardial infarction. When the protective device is a balloon, the balloon is inserted and inflated at a point distal to the treatment site or lesion site. Therapy is then performed at the ~~treatment~~ site and the balloon acts to block all blood flow, which prevents emboli from traveling

beyond the balloon. Following treatment, some form of particle removal device must be used to remove the dislodged emboli prior to balloon deflation. U.S. Patent No. 5,843,022 uses a balloon to occlude the vessel distal to a lesion or blockage site. The occlusion is treated with a high pressure water jet, and the fluid and entrained emboli are subsequently removed via an extraction tube. U.S. Patent No. 6,135,991 describes the use of a balloon to occlude the vessel allowing blood flow and pressure to prevent the migration of emboli proximally from the treatment device. While effective as a protective device, balloons may result in damaged tissue due to lack of blood flow downstream of the treatment area due to the time required to inflate and deflate the balloon.

To overcome this disadvantage, most development in relation to occlusive devices has focused on devices that screen the blood through a filter arrangement. An early arterial filtering system utilizing a balloon catheter with a strainer device is described in U.S. Patent No. 4,873,978. The device is inserted into a vessel downstream of the treatment site. The strainer responds to actuation of a separately introduced control cable to open and close a plurality of tines capable of retaining dislodged particles. After treatment, the strainer is collapsed and the entrapped emboli are removed from the body. The additional wire, however, creates additional complexity for the user.

More recently, filter designs have been deployed through the use of a single guidewire in which the filter device is transported to the deployment area within a sheath or catheter. Typical filters have either an umbrella shape to capture emboli or a tube shape in which the proximal end contains larger openings than the distal end so as to allow the blood and debris to enter the filter. The filter thus presents an operational face to the flow of blood within the vessel as provided by

the distal end of the tubular filter that is concave in orientation. Particles are captured within the concave face of the filter and are then retracted out of the vessel when the entire device is removed from the body.

One of the challenges regarding filters is the manner in which ~~it~~ a filter is transported to and from the area of interest. U.S Patents Nos. 6,042,598, 6,361,546, 6,371,970, 6,371,971 and 6,383,206 describe various examples of filter arrangements that are to be deployed through a sheath, while U.S. Patents Nos. 6,080,170, 6,171,328, 6,203,561, 6,364,895, and 6,325,815 describe filters that are deployed by a catheter. For example, U.S. Patent No. 6,371,971 describes a blood filter positioned by way of a single guidewire, covered by a sheath for advancement through a vessel ~~the channel~~. The sheath compresses ~~the~~ struts of the filter while in transit. An interventional procedure requires deployment of the sheath along a guidewire downstream of the vascular occlusion. The sheath is retracted and the filter expands to a predetermined size. The filter is retrieved after the procedure by deploying the sheath back down the guidewire, capturing the filter and removing the system from the patient.

The disadvantage associated with this type of filter is the added thickness of the device due to the use of a sheath to deploy the filter. Typical sheath diameters exceed 0.040 inch~~es~~. Insertion of the sheath can damage the vessel during routing and deployment to the occluded area and during removal. Moreover, the bulky sheath protecting the filter can hamper the debris removal or cause further embolization.

There is a need then for a protective device capable of embolization protection for vascular and arterial procedures without the design limitations of the existing approaches. Occlusive balloons can remain in place too long, thus increasing the risk of vessel damage

downstream of the occlusion. Protective filters avoid this problem but suffer from complicated deployment and retraction schemes. Moreover, existing filters are limited in range due to the filter framework, which also may result in vessel damage. It would be desirable to provide an occlusive filter device that is easily deployable along a single guidewire without a large diameter sheath ~~along a single guidewire,~~ and that reduces the potential for vessel damage.

SUMMARY OF THE INVENTION

The present invention is a ~~guidewire~~ protective system or apparatus for use in vascular procedures comprising a tubular guidewire; a control cable disposed within the lumen of ~~a~~ the tubular guidewire; and a sheathless ~~convex protective~~ filter distally coupled to the control cable and proximally coupled to the tubular guidewire. The sheathless filter radially expands as the distal end of the sheathless filter is drawn toward the proximal end of the sheathless filter in response to displacement of the control cable relative to the tubular guidewire. The primary filter action is provided by the proximal outer convex surface of the sheathless filter, which is the first surface to come in contact with the flow of blood within ~~the~~ a blood vessel.

In a preferred embodiment, the sheathless filter is comprised of a braided ~~N~~ n itinol wire ~~skeleton~~ ~~frame~~ framework in the form of a tube to which ~~other fibers~~ woven strands are ~~woven~~ applied to create a filter mesh. In one embodiment, the ~~other fibers~~ woven strands are multifilament polymer fibers. In an alternate embodiment, the ~~other fibers~~ woven strands are ~~other~~ n itinol wires of different diameters. ~~A~~ The distal end of the control cable is attached to the distal end of the ~~tubular mesh~~ sheathless filter ~~. The~~ and the proximal end of the control cable extends beyond the proximal end of the tubular guidewire for access. Pulling the proximal end of the control cable draws the distal end of the ~~tubular mesh~~ sheathless filter toward~~s~~ the proximal end~~,~~ of the sheathless filter which is attached to the tubular guidewire. The sheathless filter expands radially until it either fills the blood vessel or reaches a maximum

expansion point at which filter mesh openings are still smaller than the smallest expected particle size of clinical significance. The sheathless filter may be locked in place to prevent premature closure of the sheathless filter. In one embodiment, the sheathless filter is provided with a radiopaque marker that provides an indication of the position and deployment state of the sheathless filter under fluoroscopy.

Unlike existing filters that have a concave operational surface, the proximal ~~face~~ exterior surface of the deployed sheathless filter of the present invention has a convex shape that provides a first or primary filter surface. Particle removal from the convex filter surface is preferably accomplished in conjunction with a catheter-based aspiration device, such as a ~~T~~thrombectomy ~~D~~device, U.S. Patent No. 5,370,609, commonly referred to as an AngioJet®. The use of an aspiration device enables removal of the majority of particles trapped by the convex ~~face~~ filter surface prior to retraction of the sheathless filter through an evacuation lumen. Should debris escape the mesh of the proximal convex ~~front~~ primary filter surface, the interior distal ~~face~~ surface of the sheathless filter creates a ~~second~~ secondary concave ~~back~~ filter surface which also traps debris. Extraction requires reducing the sheathless filter diameter by retracting the ~~Nitinol~~ control cable. The collapsed ~~tubular~~ sheathless filter holds debris trapped by the secondary filter surface during the removal process.

In a preferred embodiment, the tubular guidewire is advanced over the control cable in a slidable fashion. A short ~~intermediate~~ tube, disposed ~~between~~ intermediate the control cable and the tubular guidewire at the proximal end of the tubular guidewire, provides resistance to the control cable movement. The resistive force maintains the position of the control cable relative to the tubular guidewire during a procedure. Alternatively, the sheathless filter may be locked into position either by a torque device tightened over the tubular guidewire, by a clamp, or by an interference fit ~~of a feature of~~ created by a projection on the control cable mating with the inner diameter surface of the tubular guidewire. At the distal end of the control cable, radial expansion of the sheathless filter is limited to maintain appropriate maximum allowable mesh

spacing. A stop is crimped onto the control cable beyond the distal end of the tubular guidewire. The ~~crimp~~ stop blocks control cable ~~advancement~~ retraction into the tubular guidewire at the acceptable limit of deployment. Alternatively, the location at which the proximal end of the sheathless filter is joined to the tubular guidewire can be used to control the extent of deployment.

In one embodiment for coronary vascular procedures, the tubular guidewire ~~assembly~~ preferably has an effective length of ~~190~~ 180 cm. The outer diameter of the ~~shaft~~ tubular guidewire would be 0.014 inch~~es~~. Starting profile of the sheathless filter is 0.030 inch~~es~~ and fully expanded profile would be 0.3 inch~~es~~. There is no deployment delay as with inflating a balloon. Deployment is immediate upon activation of the control cable. This embodiment in combination with an aspiration debris removal device is particularly adapted to provide distal embolization protection in debulking vascular interventional procedures, such as those involving a blocked saphenous vein coronary bypass graft. The aspiration debris removal device removes the majority of particles while the sheathless filter captures the remainder. Alternatively, the present invention may be configured and sized for use in peripheral vascular procedures or ~~neural vascular~~ neurovascular procedures.

The advantage of the ~~guidewire~~ protective system or apparatus of the present invention is that ~~the protective device~~ it behaves like an ordinary guidewire yet does not require a bulky sheath for deployment or retrieval. Unlike balloon occlusive devices that block a vessel, the sheathless filter of the present invention ~~serves as a filter that~~ allows for the continuous flow of blood, thus decreasing potential damage to ~~downstage~~ downstream tissue. Unlike other filters, the sheathless filter of the present invention has a variable diameter based on the extent of deployment, which further results in a range of filtration capabilities. Moreover, the flexible nature of the filter mesh conforms to vessel shape and the "soft"

multifilament polymer fibers create less damage. There are no complicated mechanical arrangements or valve systems internal or external to the ~~guidewire~~ protective system or apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a ~~perspective~~ side view of the ~~present invention~~ protective system or apparatus prior to expansion of the sheathless filter ~~assembly~~.

FIG. 2 is a ~~perspective~~ side view of the ~~present invention~~ protective system or apparatus after expansion of the sheathless filter ~~assembly~~.

FIG. 3 is a close-up ~~perspective~~ side view of a portion of the filter ~~assembly of the present invention~~ protective system or apparatus featuring the sheathless prior to expansion.

hyphen

FIG. 4 is a close-up ~~perspective~~ side view of a portion of the filter ~~assembly of the present invention~~ protective system or apparatus featuring the sheathless partially expanded.

hyphen

FIG. 5 is a close-up ~~perspective~~ side view of a portion of the filter ~~assembly of the present invention~~ protective system or apparatus featuring the sheathless at full operational expansion.

FIG. 6 is a ~~close-up perspective~~ detail view of the braided wire ~~mesh~~ framework and filter mesh of the sheathless filter ~~assembly of the present invention~~.

FIG. 7 is a ~~perspective~~ side view of the ~~present invention~~ protective system or apparatus with a clamp attached to the control cable.

FIG. 8 is a side view of another embodiment of ~~the present invention~~ protective system or apparatus.

FIGS. 9A, 9B and 9C are detailed cross sectional views of the sheathless filter of the embodiment shown in FIG. 8.

FIG. 10 is a detailed ~~cross-sectional~~ side view of the ~~distal~~ flexible guidewire tip of the embodiment shown in FIG. 8.

FIG. 11 is a ~~detailed~~ magnified view of a section of the filter mesh of one embodiment of the ~~protective~~ sheathless filter.

FIG. 12 is a detailed view of the proximal attachment of the ~~protective~~ sheathless filter to the tubular guidewire.

~~FIGs. 13 and 14 are cross-sectional views of pieces of a clamp arrangement for use with one embodiment of the present invention.~~

~~FIGs. 15 and 16~~ FIGS. 13 and 14 are cross sectional views of an interference ~~feature for use~~ fit used with one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is a ~~guidewire~~ protective system or apparatus for use in vascular procedures. The ~~invention~~ protective system or apparatus includes a tubular guidewire having a proximal end, a distal end, and a lumen ~~. A~~ ; a control cable, having a proximal end and a distal end, ~~is~~ disposed in the lumen of the tubular guidewire ~~.~~ ; and a ~~A~~ sheathless ~~protective~~ filter distally coupled to the control cable and proximally coupled to the tubular guidewire. The sheathless filter expands in response to the displacement of the control cable relative to the tubular guidewire such that the sheathless filter presents at least a proximal-exterior convex primary filter surface to the flow of blood in a blood vessel. In one embodiment, the sheathless ~~protective~~ filter has a distal interior ~~face~~ concave surface which provides a secondary ~~filtering surface. The distal interior face presents a concave~~ filter surface to the flow of blood within a blood vessel.

The ~~guidewire protection~~ protective system or apparatus is preferably provided with a mechanism or means for resisting displacement of the control cable relative to the tubular guidewire. In one embodiment, ~~an~~

a short tube ~~intermediate shaft~~ is disposed intermediate ~~between~~ the tubular guidewire and the control cable at the proximal end of the tubular guidewire. The short tube ~~intermediate shaft~~ is crimped to resist movement of the control cable. When the control cable is adjusted, it thus remains in place due to the resistance created by the short tube ~~intermediate shaft~~. In another embodiment, the control cable contains a stop so as to limit displacement. In a further embodiment, a clamping mechanism is used to selectively clamp the control cable to resist displacement ~~along the guidewire~~. Alternatively, ~~a feature of~~ the control cable may be equipped with structure ~~designed~~ to provide an interference fit with the ~~an~~ interior of the lumen of the tubular guidewire.

The sheathless ~~occlusive~~ filter is preferably comprised of ~~a~~ wire elements ~~mesh~~ that form~~s~~ a tubular braided wire framework over which other members are woven to create the filter mesh ~~surface~~. In one embodiment, the other members ~~fibers~~ are multifilament polymer fibers. In an alternate embodiment, the other members ~~fibers~~ are ~~other~~ nitinol wires of different diameters. The wire elements used for the braided wire framework are ~~is~~ biocompatible and have ~~has~~ material properties consistent with that needed to create a tubular braided structure. For example, nitinol wire elements could be used in this application. In an alternate embodiment, the multifilament polymer fibers that create the filter mesh ~~surface~~ could be woven into a fabric and then attached to the braided wire framework ~~mesh~~.

To allow deployment of the sheathless filter ~~guidewire protection system~~, the control cable is longer than the tubular guidewire and has a smaller diameter than the inner diameter of the tubular guidewire. Preferably, the outer diameter of the tubular guidewire is 0.018 inch~~es~~ or less. In addition, the proximal end of the tubular guidewire will be free of any mechanical connections and obstructions so as to enable the tubular guidewire to function as a conventional exchange guidewire while the sheathless filter is deployed.

The present invention provides a method of preventing plaque, thrombus or ~~other~~ grumous material and debris from flowing downstream during vascular procedures. The method

includes guiding a tubular guidewire into a blood vessel ~~A protective~~ until a sheathless filter ~~is then positioned.~~ located at the ~~proximate a~~ distal end of the tubular guidewire ~~and~~ is positioned distal to the region of the blood vessel to be treated. A control cable coaxially disposed within the tubular guidewire and affixed to the sheathless filter is displaced, thus expanding the ~~protective~~ sheathless filter to a deployed state which spans the diameter of the blood vessel. The tubular guidewire is clamped at the proximal end so as to prevent unwanted further displacement of the control cable during the vascular procedure. In a preferred embodiment, the tubular guidewire has ~~a~~ an outer diameter of up to 0.018 inch~~es~~ and is made of ~~a~~ ~~N~~nitinol or comparable material.

A catheter is introduced over the proximal end of the tubular guidewire and is advanced to the region of the blood vessel to be treated. A vascular procedure is then performed in the area using the catheter. The present invention may be incorporated with a vascular procedure such as an asymmetric water jet atherectomy wherein a jet directs a working fluid at a velocity sufficient to generate a stagnation pressure for removal of ~~a~~ ablated deposit debris. The catheter is also used to remove material captured by the proximal exterior convex ~~proximal face~~ primary filter surface of the sheathless filter. The control cable is then released ~~from the crimped guidewire~~ thus contracting the sheathless filter. The tubular guidewire with sheathless filter is then guided out of the blood vessel.

In the preferred method, the ~~protective~~ sheathless filter is comprised of a braided wire ~~mesh~~ framework over which other members are co-braided to create a barrier to particles. The braided wire ~~mesh~~ framework is attached to the distal end of the control cable and to the proximate end of the tubular guidewire. The braided wire ~~mesh~~ framework and co-braided other members are selectively spaced so that particles are captured. In one embodiment, the co-braided other ~~fibers~~ members are multifilament polymer fibers. In an alternate embodiment, the co-braided other ~~fibers~~ members are ~~other~~ ~~N~~nitinol wires of different diameters. Preferably, the ~~fibers~~ co-braided other members and braided wire ~~mesh~~ framework are spaced to capture particles of at least 250 microns and more preferably down to 100-150 microns. In the

alternative, the multifilament polymer fibers are woven into a fabric and then attached to the braided wire framework ~~mesh~~. Before deployment, the ~~occlusion~~ sheathless filter has a closed position in which the braided wire ~~mesh~~ framework and multifilament polymer fibers or other members are disposed generally parallel to the control cable and tubular guidewire so that the ~~present invention~~ sheathless filter can be inserted into a blood vessel.

The present invention is also a system or apparatus for filtering emboli from the blood of a patient generally coincident to a vascular procedure. The system or apparatus includes blood vessel lumen opening means, debris filtering means, and emboli evacuation means. To open the lumen of a blood vessel, a catheter ~~with~~ is used which has a distal end having one or more orifices from which a working fluid, such as saline under high pressure, is directed in the form of a fluid jet at a deposit within the blood vessel. The fluid jet impacts the deposit longitudinally so as not to damage the blood vessel. The impact dislodges the deposit and creates a plurality of debris particles.

The blood vessel lumen opening means further includes a tubular member containing a hypotube. Preferably, the tubular member is used as an evacuation lumen. The ~~lumen~~ hypotube further includes one or more high velocity fluid jets directed to strike a portion of the tubular member. The high velocity fluid jets create~~s~~ a localized low pressure region which draws the debris particles to the fluid jets and subsequently down the exhaust lumen.

The debris filtering means includes ~~a tube-shaped~~ the sheathless filter which is advanced distally of the deposit by ~~a~~ the tubular guidewire. The ~~tube-shaped~~ sheathless filter is comprised of a braided wire ~~mesh~~ framework over which a plurality of strands are co-braided. The braided wire ~~mesh~~ framework is radially deployed. The ~~tube-shaped filter~~ braided wire framework is fixed at ~~a~~ its proximal end to the tubular guidewire and the braided wire ~~mesh~~ framework is fixed at ~~the~~ its distal end to the control cable. In a non-deployed state, the individual wire elements of the braided wire ~~mesh~~ framework lie generally parallel to the control cable and the tubular guidewire.

The ~~tube-shaped~~ sheathless filter can be selectively deployed so as to radially expand to ~~encompass~~ span the diameter of the blood vessel. At a lower deployment limit, no fluid is able to pass through the sheathless filter. In a first embodiment, the lower deployment limit for the sheathless filter would be 3 mm. Likewise, the ~~tubular~~ sheathless filter has an upper deployment limit based on the unoccupied distance between any two of the strands. This unoccupied distance is defined as a pore size. In a first embodiment, the maximum pore size is 0.010 inch in each direction of the opening so that the ~~tube-shaped~~ sheathless filter would be able to capture particles of 250 microns or greater. Alternatively, the maximum pore size is 0.005 inch~~es~~ so that the sheathless filter is able to capture particles of 100-150 microns or greater. In an alternate embodiment, the multifilament fibers are woven into a fabric prior to attaching them to the braided wire ~~mesh~~ framework.

In one embodiment, the debris capturing means includes two filtering surfaces. First, a proximal exterior convex ~~face~~ filter surface of the ~~tube-shaped~~ sheathless filter blocks the passage of particles immediately downstream of the vascular procedure. A second debris capturing means includes an interior concave filter ~~face~~ surface at the distal end of the ~~tube-shaped~~ sheathless filter.

The outer diameter of the ~~tube-shaped~~ sheathless filter is smaller than the inner diameter of the blood vessel prior to deployment. In a first embodiment, it is envisioned that the ~~tube-shaped~~ sheathless filter will have an outer diameter of no more than ~~0.046 inches~~ 0.038 inch prior to deployment.

In operation, it is envisioned that emboli evacuation would include removing the displaced emboli from the proximal exterior convex ~~face~~ filter surface of the ~~tube-shaped~~ sheathless filter through the use of the evacuation lumen.. The evacuation lumen is attached to a vacuum pump which provides suction at the distal end. In addition, the evacuation lumen may be driven by the fluid jets which create a stagnation pressure upon striking the mouth of the evacuation lumen. Emboli evacuation is

further accomplished due to the interior concave ~~face~~ filter surface at the distal end of the ~~tube-faced~~ sheathless filter catching emboli that are not trapped by the proximal convex ~~face~~ filter surface. The sheathless filter is contracted and removed from the body upon completion of the procedure. The trapped emboli are maintained within the sheathless filter body during the removal procedure.

Referring now to FIGS. 1-2, the overall structure and operation of a ~~guidewire filter~~ protective system or apparatus 20 in accordance with the present invention will be described. The ~~guidewire filter~~ protective system or apparatus 20 ~~in accordance with one embodiment~~ includes a tubular guidewire ~~assembly~~ 30, ~~protective~~ a sheathless filter ~~assembly~~ 50, and ~~a clamp 70~~ control cable 38.

The tubular guidewire ~~assembly~~ 30 ~~is a tubular member that~~ includes a proximal ~~portion~~ end 32 and a distal ~~portion~~ end 34. As used in the present invention, the terms proximal and distal will be used with reference to an operator ~~of the device~~, such that ~~a~~ the distal ~~portion~~ end 34 of the tubular guidewire ~~assembly~~ 30, for example, is the portion first inserted into a blood vessel, and the proximal ~~portion~~ end 32 is the portion which remains exterior to the patient and is therefore closer to the operator ~~of the device~~.

The tubular guidewire ~~assembly~~ 30 ~~is comprised of a guidewire 36, a~~ receives the control cable 38 and an optional ~~intermediate shaft~~ short tube 40. ~~The guidewire 36 is a tubular member having a proximal end 32, which remains exterior to the patient, and a distal end 34 which in operation is proximate a vessel of the patient.~~

The control cable 38 is a wire having a proximal end 48 and a distal end 49 slidably disposed within the lumen of the tubular guidewire ~~36~~ 30. The control cable 38 extends proximally and distally beyond the respective proximal and distal ends 32 and 34 of the ~~lumen 36~~ tubular guidewire 30. The total length of control cable 38 is longer than the length of the tubular guidewire ~~36~~ 30 to provide for the sheathless filter ~~assembly~~ 50 at the distal end 34 and a gripping region 46 at

the proximal end 32. Exact lengths for the respective elements ~~is~~ are determined by the required path to reach the occlusive site within the patient.

In a preferred embodiment, a flexible guidewire tip 60 is positioned in a sleeve 62 which is attached to the control cable 38 at the distal end 49 of control cable 38 to assist in deployment of the protective system or apparatus 20 through ~~the~~ a blood vessel. In one embodiment, a stop ~~rod~~ 66 is crimped on to proximal end 48 of control cable 38 to prevent the control cable 38 from completely sliding into the lumen of tubular guidewire ~~36~~ 30.

In one embodiment, travel of the control cable~~s~~ 38 ~~travel~~ is restricted by ~~an intermediate shaft~~ a short tube 40 disposed within the lumen of tubular guidewire ~~36~~ 30 at the proximal end 32. The ~~intermediate shaft~~ short tube 40 ~~is a tubular member with~~ has an inner diameter slightly larger than the diameter of control cable 38 and an outer diameter slightly smaller than the inner diameter of tubular guidewire ~~36~~ 30. The ~~intermediate shaft~~ short tube 40 increases the resistive effect on the control cable 38 so as to maintain position relative to tubular guidewire ~~36~~ 30. ~~A relatively~~ The short ~~intermediate shaft~~ tube 40 ~~of~~ ordinarily is less than one inch in length ~~is used to create the resistive effect~~. The tubular guidewire ~~36~~ 30 is crimpable relative to the ~~intermediate shaft~~ short tube 40 ~~as it is presumed a clamping tool 70 may also be utilized to maintain position~~.

Alternatively, the ~~intermediate shaft~~ short tube 40 could be eliminated and position then maintained by crimping the proximal end 32 of the tubular guidewire ~~36~~ 30 to the control cable 38, by using a torque device, by using a clamp, by the interaction of a ~~feature~~ projection on the control cable 38 with the interior diameter surface of the tubular guidewire ~~36~~ 30, or simply by maintaining relative position manually. Although the diameter of the control cable 38 could be of any size consistent with effective use of ~~a~~ the tubular guidewire 30, it will be understood that the larger diameter creates a resistive effect on the tubular guidewire ~~36~~ 30, or ~~intermediate shaft~~ short tube 40, so as to maintain position relative to ~~said~~ the tubular guidewire ~~36~~ 30 when force is removed.

A ~~protective~~ sheathless filter ~~assembly~~ 50 having a proximal end 52 and a distal end 54 is located at the distal end 34 of tubular guidewire ~~assembly~~ 30. The ~~protective~~ sheathless filter ~~assembly~~ 50 is preferably comprised of a braided wire ~~mesh~~ framework 56 over which a plurality of multifilament polymer fibers ~~58~~ are braided to form a filter mesh 58. Alternatively, the braided wire ~~mesh~~ framework 56 may support a filter mesh 58 of other fibers or wires, such as ~~a~~ nitinol ~~mesh of~~ wires 58, as shown in FIG. 11. The proximal end 52 of the sheathless ~~occlusive~~ filter ~~assembly~~ 50 is laser-welded to the distal end ~~44~~ 34 of tubular guidewire ~~30~~ 30 as shown in FIG. 12, for example, while the distal end 54 of the sheathless ~~occlusive~~ filter ~~assembly~~ 50 is laser-welded to the distal end 49 of control cable 38. In one embodiment, a control cable stop 68 (see FIGS. 4 and 5) is disposed on control cable 38, between the proximal end 52 and distal end 54 of the sheathless filter ~~assembly~~ 50, so as to limit the travel of control cable 38. Exact location of the stop 68 is determined by the filter spacing created upon radial expansion of the braided wire ~~mesh~~ framework 56 as compared to the particle size to be filtered.

The individual wire elements 64 of braided wire ~~mesh~~ framework 56 are disposed parallel to tubular guidewire ~~30~~ 30 and control cable 38 at the points of attachment so as to present a minimal crossing profile. Individual ~~monofilament~~ polymer fibers ~~58~~ are co-braided about the braided wire ~~mesh~~ framework 56 to increase cross-section coverage without the stiffness associated with the wire elements ~~wires~~ 64. Alternatively, ~~the~~ other members ~~58 may be~~ comprised of smaller diameter strands or wires that exhibit more flexibility than the ~~wires~~ wire elements 64 associated with the braided wire framework ~~64~~ 56 may be used. In one embodiment, the sheathless filter ~~assembly~~ 50 may be coated with a hemocompatible compound to minimize shear activation of platelets.

During interventional procedures involving carotid arteries and saphenous vein bypass grafts, embolic particles may be liberated causing adverse complications if preventive means are not in place. In a preferred embodiment, as illustrated in FIGS. 1-6, the ~~guidewire filter~~

~~Occlusion~~ protective, or apparatus system 20 provides embolic protection. In one embodiment, the tubular guidewire ~~36~~ 30 is formed of a ~~N~~ nitinol ~~shaft~~ tube having an outer diameter of 0.014 inch~~es~~, an inner diameter of 0.010 inch~~es~~, and a length of 180 cm. In an alternate embodiment as shown in FIG~~s~~S. 8-10, the tubular guidewire ~~36~~ 30 is formed of a braided polyimide tube having an outer diameter of 0.015 inch~~es~~, an inner diameter of 0.011 inch~~es~~, and a length of 180 cm, such as available from MedSource Technologies, Trenton, Georgia. In one embodiment, the control cable 38, is formed of a ~~N~~ nitinol ~~rod~~ wire having a diameter of 0.008 inch~~es~~ and a length of 190 cm. In an alternate embodiment, the control cable 38 is formed of a Teflon® coated stainless steel ~~rod~~ wire having a diameter of 0.095 inch~~es~~. The control cable ~~core~~ 38 is disposed coaxially with the tubular guidewire ~~36~~ 30. Although the length of the tubular guidewire ~~36~~ 30 could be any length, it will be understood that it will be shorter than the length of control cable 38. In a first embodiment, the control cable 38 will be at a minimum of 10 cm longer so as to provide for the attachment of the sheathless filter ~~assembly~~ 50 at the distal ~~portion~~ end 34 and a gripping ~~area~~ region 46 at the proximal ~~portion~~ end 32. In one embodiment, ~~intermediate shaft~~ short tube 40, is also preferably made of ~~N~~ nitinol with a length of 0.05 inch~~es~~.

As shown in FIG. 1, the flexible guidewire tip 60 is disposed at the distal end ~~54 of the guidewire assembly 30~~ 49 of the control cable 38. The flexible guidewire tip 60 is preferably a platinum coil 61 with a stainless steel core 63 having a maximum diameter of 0.018 inch~~es~~ and a length of 1.0 inch. Attachment of flexible guidewire tip 60 is accomplished in one embodiment by a stainless steel sleeve 62 that is laser-welded to control cable ~~core~~ 38. A crimp is applied to the sleeve 62 to hold the flexible guidewire tip 60 in place. FIG. 10 shows an alternate embodiment ~~of the construction of the~~ flexible guidewire tip ~~60 where~~ 60a wherein the ~~tip~~ core thereof is fabricated as part of the control ~~rod~~ cable 38.

In one embodiment, at the proximal end 48 of control cable 38, a ~~cable~~ stop ~~rod 68~~ 66 is attached. In this embodiment, ~~cable~~ stop ~~rod 68~~ 66 is 0.25 inch long with a diameter of 0.014 inch, which is equal to the diameter of tubular guidewire 30. The ~~cable~~ stop ~~rod 68~~ 66 is crimped onto control cable 38 and serves to keep the proximal end 48 of the control cable 38 from entering into the tubular guidewire 30.

~~In an alternate embodiment as shown in FIGs. 13 and 14, a hemeostatis-like clamp arrangement 80 is utilized on the proximal end 48 of guidewire assembly 20 to secure the control cable 38 relative to the tubular guidewire 30. The clamp arrangement 80 preferably consists of an actuator assembly 82 that is secured to the tubular guidewire 30 and an indicator assembly 84 that clamps onto the control cable 38 by rotation of a knob member 86 that pinches control cable 38 in a wedge structure 88. In one embodiment, the distal end of actuator assembly 82 is provided with structure 90 that attaches the actuator assembly 82 to the guidewire by a torque device, such as a collet clamp. Preferably, both the actuator assembly 82 and the indicator assembly 84 have mated threads 92 that permit the actuator assembly 82 to threadably receive the indicator assembly 84. The indicator assembly 84 preferably includes visible markings at 94 that indicate to an operator the extent of the deployed state of the filter device 50 based on the number of turns of knob 86 as the indicator assembly 84 is unscrewed and control cable 38 is displaced relative to the tubular guidewire 30. It will be understood that alternative arrangements for securing the control cable 38 and tubular guidewire 30 can be used with the indicator assembly such as a pin vise or bearing arrangment, and that a latch, ratchet or other step-wise mechanical interface could be utilized in place of the threads 82.~~

~~In~~ Another embodiment as shown in FIGS. 13 and 14 features an interference fit between ~~a~~ the proximal end 48 of control cable 38 and ~~a~~ the proximal end 32 of tubular guidewire 30 that

effectively locks the ~~protective~~ sheathless filter ~~assembly~~ 50 into a minimum diameter or undeployed state during insertion ~~of the guidewire assembly~~. This feature is particularly useful to ~~i~~ensure that the sheathless filter ~~assembly~~ 50 remains in as unobtrusive a state as possible during passage ~~of the distal tip 34 of the guidewire~~ through lesions or tortuous areas of the blood vessel undergoing a vascular procedure. ~~In~~ The interference ~~feature~~ fit is created by a projection 96 on the control cable 38, which frictionally interfaces with the proximal opening of the lumen of the tubular guidewire 30 to secure the relative position between the two. In this embodiment, the ~~interference feature~~ projection 96 is a frustoconical-shaped member that extends beyond the outer diameter of the control cable 38. Numerous other shapes and configurations such as a lipped configuration or a ratchet arrangement could also be used.

~~Filter assembly~~ Sheathless filter 50 is comprised of a plurality of ~~filter wires~~ wire elements 64, which form a braided wire framework 56 to support a plurality of polymer fibers or strands formed into a filter mesh 58, as illustrated in FIG. 6. In a first embodiment, the polymer fibers or strands ~~58~~ are co-braided around the braided wire ~~mesh~~ framework 56. The ~~wires~~ wire elements 64 are made of ~~N~~nitinol, a super-elastic nickel titanium alloy, which is the preferred material because it is easy to braid and biocompatible. A plurality of laser-welds are applied at the ~~distal filter~~ proximal end 52 and ~~proximal filter~~ distal end 54 to hold the ends of ~~filter wire~~ the wire elements 64 in position and prevent fraying. At least two welds are performed on each wire element 64 at each end so as to hold ~~the~~ each wire element 64 as small as possible, thus presenting a minimal profile ~~in that deployment without a sheath~~. Alternatively, adhesive bonds or mechanical interconnections may be used in place of or in addition to welding to secure the sheathless filter ~~assembly~~ 50. In an alternate embodiment as shown in FIGS. 11 and 12, the strands forming the filter mesh 58 are also comprised of ~~N~~nitinol wire having a smaller diameter (e.g., 0.008 ~~"~~ INCH) than the ~~wires~~ Nitinol wire elements 64 (e.g., 0.012 ~~"~~ INCH).

It is expected that the radial expansion of the sheathless filter ~~assembly~~ 50 will have an upper and lower limit based on blood flow requirements at the lower limit and the ability to stop particles of an expected size at the upper limit. In a first embodiment, the lower limit of expansion would provide filtration in vessels as narrow as 3 mm. In order to filter particles of 250 microns or larger, the maximum allowable mesh gap would be 0.01 inch~~es~~ which corresponds to a maximum deployment diameter of 0.3 inch~~es~~. In the closed position, as depicted in FIG. 3, the maximum diameter of the non-deployed sheathless filter 50 is 0.038 inch~~es~~.

In another embodiment as shown in FIGS. 8-12, the sheathless filter 50 ~~assembly~~ is designed to filter particles down to a size of between 100-150 microns. The inter-mesh spacings required for such a filtration effect range between 0.004 inch~~es~~ and 0.008 inch~~es~~, as can be seen in FIG. 11, for example. In this embodiment, the expansion size of the sheathless filter ~~assembly~~ 50 in a deployed state is selected among a plurality of sizes (e.g., 2-4 mm diameter vessels, 4-6 mm diameter vessels, 6-8 mm diameter vessels) to control the filtration effect of a given sized sheathless filter 50 by providing a known range of diameters in the deployed state for which the inter-mesh spacings necessary to achieve the desired filtration effect can then be chosen. In tests with the sheathless filter 50 ~~assembly~~ of the present invention deployed within a 6.2 mm acrylic tube, polymer particles of ~~know~~ known size were introduced into a fluid flow simulating blood to determine the effectiveness of the sheathless filter 50 ~~assembly~~. When particles of a size of 200 microns were used in this test, 100% of the particles were trapped by the ~~first~~ convex primary filter surface of the sheathless filter 50 ~~assembly~~. When the particle size was reduced to 157 microns, 50% of the particles were trapped by the ~~first~~ convex primary filter surface, 40% were trapped by the ~~second~~ concave secondary filter surface and approximately 10% of the particles flowed through the sheathless filter 50 ~~protective device~~. It will be seen that the sizes of the inter-spacing pores may be adjusted if protection for

smaller size particles is desired to improve the effectiveness of the ~~protective device~~ sheathless filter 50 for particles at those smaller sizes while potentially reducing the flow of blood due to the use of the smaller size pores.

To limit radial expansion of sheathless filter ~~assembly~~ 50, in one embodiment ~~control cable~~ stop 68 (see FIGS. 4 and 5) is coaxially disposed on control cable 38 between the proximal and distal ends 52 and 54 of sheathless filter ~~assembly~~ 50. ~~Cable~~ Stop 68 is a stainless steel tube crimped onto control cable 38 with an outer diameter of 0.012 inch~~es~~ which stops the control cable 38 from traveling into the lumen of tubular guidewire ~~34~~ 30.

The fibers, strands or ~~wires 58~~ of the filter mesh 58 and ~~strands 60~~ the wire elements 64 of the braided wire framework 56 lie generally parallel to control cable ~~core~~ 38 when inserted into ~~in~~ a blood vessel. As control cable ~~core~~ 38 is proximally extended, distal ~~filter~~ end ~~52~~ 54 is drawn toward stationary proximal ~~filter~~ end 52 ~~54~~. Initial displacement, as depicted in FIG. 4, for example, creates a narrow tube as the sheathless filter 50 ~~wires expand~~ expands radially in an elastic manner to form a thin tube. As the control cable ~~core~~ 38 is further displaced, the sheathless filter 50 ~~wires 58 continue their radially~~ continues its radial expansion, as depicted in FIG. 5, until ~~reaching~~ stop ~~62~~ 68 reaches distal end 34 or filling of the blood vessel takes place.

It will be understood that the weave of sheathless filter ~~assembly~~ 50 may be varied in a number of ways including: ~~change~~ changing the number of filaments per strand of the multifilament polymer fibers; ~~change~~ changing the diameter of the polymer filaments; ~~change~~ changing the number of ~~N~~nitinol ~~strands~~ wire elements which form the braided wire framework 56 ~~mesh skeleton~~; ~~change~~ changing the diameter of the ~~N~~nitinol wires and/or ~~wire elements~~ ~~strands~~; and ~~change~~ changing the design of the tubular weave. A further advantage to this design is the "softness" created by the polymer fibers as they interact with the blood vessel. Varying the ~~N~~nitinol ~~strands~~ wire elements has a direct effect on the stiffness of the sheathless filter 50 and the "softness." However, the number of ~~N~~nitinol ~~strand number~~ wire elements must be sufficient to adequately constrain the multifilament polymer fibers. Clearly, the options described above may

be used to tighten or relax the weave of the sheathless 50 filter. Furthermore, the options may be combined to achieve comparable results.

In practice, medical personnel gain access to the blood vessel lumen through which the ~~guidewire assembly~~ protective system or apparatus 20 will travel. The ~~guidewire filter~~ protective system or apparatus 20 is removed from biocompatible packaging. ~~Guidewire~~ Flexible guidewire tip 60 is inserted into the blood vessel lumen and is manipulated to a point beyond the vessel occlusion. The control cable 38 is drawn ~~distally~~ proximally from the tubular guidewire ~~38~~ 30 so as to radially deploy the sheathless filter 50 within the blood vessel lumen. A rapid exchange device, such as a stent catheter or thrombectomy device, is then deployed on the tubular guidewire ~~36~~ 30 with the sheathless filter ~~assembly~~ 50 in a deployed state. As illustrated in FIG. 7, a clamp 70 is then applied to the ~~guidewire assembly 20~~ control cable 38 to maintain the deployed position of the sheathless filter 50 until completion of the procedure.

In a preferred embodiment of the present invention, the ~~guidewire~~ protective system or apparatus 20 is utilized ~~as the guidewire for~~ in an ather~~o~~ectomy or thrombectomy procedure of the type described in U.S. Patents Nos. 5,370,609 or 5,496,267, the disclosure of each of which is hereby incorporated by reference. In each of these embodiments, the ~~guidewire~~ protective system or apparatus 20 is introduced into the patient, the sheathless filter 50 is radially deployed, and then the ather~~o~~ectomy or thrombectomy catheter arrangement is slid over the proximal end 32 of the tubular guidewire ~~assembly~~ 30 and advanced until it is proximate and proximal to the location of the sheathless filter ~~assembly~~ 50. Unlike other occlusive methods, the time period of the procedure is not constrained by concern over blockage of the blood vessel. The radial expansion of sheathless filter ~~assembly~~ 50 allows for the continual flow of blood through the spacing between individual ~~polymer fibers~~ strands of the filter mesh 58. Thus, sheathless filter ~~assembly~~

50 is preferable where ischemia is intolerable or further blood cessation would be irreparably damaging.

Preferably, an evacuation of any debris ~~or other plaque material~~ dislodged in the therapy is accomplished by the evacuation lumen incorporated within the catheter assembly of the above-referenced patents. However, should debris ~~or plaque~~ escape the evacuation lumen, the proximal exterior convex ~~proximal face 72~~ filter surface of the sheathless filter ~~assembly~~ 50 provides the primary ~~means~~ filtering surface for trapping this detritus. The distal interior concave ~~interior face 74~~ filter surface of the sheathless filter ~~assembly~~ 50 provides a ~~second~~ secondary filtering surface. Additionally, a sponge could be compressed to fit within the collapsed sheathless 50 filter ~~assembly~~. Upon deployment, the sponge would provide a third level of filtering. After completion of the procedure, the sheathless 50 filter ~~assembly~~ is returned to an undeployed state and the tubular guidewire ~~assembly 20~~ 30 and sheathless filter ~~assembly~~ 50 are retracted.

The present invention may be embodied in other specific forms without departing from the essential attributes thereof; therefore, the illustrated embodiments should be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than to the foregoing description to indicate the scope of the invention.

ABSTRACT OF THE DISCLOSURE

A ~~[guidewire protection]~~ protective system or apparatus for use in vascular procedures includes a tubular guidewire, a control cable slidable within the tubular guidewire, and a sheathless ~~[protective]~~ filter. ~~[proximate a distal end of a tubular guidewire assembly. In one embodiment, a]~~ The control cable ~~[disposed within the guidewire]~~ is attached to a distal end of the sheathless filter ~~[while]~~ and the tubular guidewire is attached to a proximal end of the sheathless filter. Selective displacement of the control cable radially expands the sheathless filter to create a ~~[tube-shaped filter having a]~~ proximal convex exterior primary filter surface that is positionable downstream from a site of a vascular procedure. ~~[In this embodiment, the]~~ The sheathless filter also presents a distal concave interior secondary filter surface. Preferably, the sheathless ~~[protective]~~ filter is constructed of a braided wire ~~[mesh]~~ framework in the form of a tube over which woven polymer fibers or strands are ~~[woven]~~ applied to create a filter mesh having a softer filter surface.